DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

Via Federal Express

Our Reference: 3003563359

December 2, 2002

John Hoogendam Jr. & Marvin L. Hoogendam
Co-owners
Hoogendam Dairy
1650 McNamara Rd.
Merced, CA 95340

WARNING LETTER

Dear Mssrs. Hoogendam:

A tissue residue report received by the Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of an illegal drug residue in a cow that originated from your dairy. As a follow-up to USDA's finding, our investigators performed an inspection of your dairy operation October 10, 15, and 18, 2002. This inspection revealed serious violations of Sections 402 and 501 of the Federal Food, Drug, and Cosmetic Act (the Act).

On August 15, 2002, you sold a calf, identified with [redacted] back tag number 4423, last four digits, for slaughter as human food. USDA analysis of tissue samples (USDA laboratory report number 441787) collected from that animal identified the presence of the drug penicillin in the kidney at 2.54 parts per million (ppm), and in the muscle at 0.07 ppm. Presently, the tolerance level for penicillin in the uncooked edible tissue of cattle is 0.05 ppm (Title 21 Code of Federal Regulations (CFR), Part 556.510). Your use of penicillin in the animal resulted in the illegal drug residue found in the kidney and in the muscle. A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful

drug residues are likely to enter the food supply. For example, our investigators noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter. Your medication records do not contain the dosages administered and the name of the individual performing the medication of each animal at your dairy.

2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs. The veterinarian's labeling specifies that milk taken from an animal must not be used for food for at least 96 hours after calving.

3. You lack an adequate system for assuring that drugs are used in a manner consistent with the directions contained in their labeling or your veterinarian's prescription labeling.

4. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

You are adulterating the drug Pharmacia & Upjohn brand Quartermaster (penicillin-dihydrosteptomycin) within the meaning of Section 501(a)(5) of the Act, in that it is a new animal drug within Section 201(v) of the Act, and is unsafe within the meaning of Section 512(a)(1)(B) of the Act since it is not being used in conformance with its approved labeling. Your practice of allowing calves intended for slaughter to suckle from their medicated mothers presents a possibility that illegal residues will occur and is the likely cause of the illegal residue found in the calve you sold for slaughter.

Additionally, you are adulterating Durvet brand Pen-Aqueous (Penicillin G Procaine) within the meaning of Section 501(a)(5) of the Act, in that it is a new animal drug within Section 201(v) of the Act, and is unsafe within the meaning of Section 512(a)(1)(B) of the Act since it is not being used in conformance with its approved labeling. Your veterinarian prescribes a dosage of 1 ml per 100 pounds of body weight, the same as the manufacturer's labeling. In addition, the manufacturer's labeling directs that no more than 10 ml be administered to any given injection site. Your practice of administering one 30 ml injection per day at one site for cows weighing 1500 - 1600 pounds results in a dosage in excess of that allowed in the labeling. This overdosing presents a possibility that illegal residues will occur.

Failure to comply with the label instructions on drugs you use to treat your animals presents the likely possibility that illegal residues will occur and makes the drugs unsafe for use. We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act are being met. Failure to achieve prompt corrections may result in enforcement action without further notice, including seizure and/or injunction.

You should notify our office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Russell A. Campbell, Compliance Officer, United States Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Sincerely yours,

Dennis K. Linsley
District Director
San Francisco District

cc: [redacted] DVM
[redacted]